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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/888,154	06/22/2001	Ramesh Wariar	112713-131	8167

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EXAMINER

BIANCO, PATRICIA

ART UNIT PAPER NUMBER

3761

DATE MAILED: 03/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/888,154

Applicant(s)

WARIAR ET AL.

Examiner

Patricia M. Bianco

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5-14,17-21,23-27,29,30 and 32-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5-14,17-21,23-27,29,30 and 32-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

Applicant filed an amendment 12/12/05 in response to the office action dated 092905. The amendment has been entered amending portions of the specification, claims 6, 13, 19, & 20 have been amended, and arguments presented.

Claims 1, 5-14, 17-21, 23-27, 29, 30, & 32-37 remain pending.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5-14, & 17-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Brown (5,036,859). Brown discloses a moisture detector and indicator that may be used to sense the presence of blood (col. 9, lines 40-42). The detector comprises electrodes (i.e. capacitive sensor) that is capable of detecting wetness due to blood, an absorbent material (i.e. barrier pad) that is capable of absorbing blood, and a cover sheet & backing layer (i.e. a holder) that are capable of holding the absorbent material and sensor over a needle. The detector is in communication with an indicator (i.e. control device) by means of electrical communication. The indicator receives a signal of wetness and alarms in response to the leak. Brown discloses that the electrodes (sensor) are separated from the body by the absorbent material, and the absorbent

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material soaks up upon a liquid if there is a leak to complete the circuit to activate the alarm. The sensor is further limited as being "capable of detecting wetness due to blood" in the claims and it has been held that the recitation that an element is "capable of" performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchinson*, 69 USPQ 138. The recitation in the claims that the holder is "adapted to secure the sensor in juxtaposition to the needle" has not been considered since it has been held that the recitation that an element is "adapted to" perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchinson*, 69 USPQ 138. Therefore, the recitation that the needle be "venous" is also not positively recited and therefore not given any patentable weight. With respect to claim 12, Brown also shows that the electrode can be on a plate (see figures 4 & 6).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

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were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 27 & 30 are rejected under 35 U.S.C. 103(a) as being obvious over Brown (5,036,859). Brown substantially discloses the invention as claimed, however, does not teach that the detector and indicator apparatus is used in a method of controlling blood loss from needle dislodgement, nor does Brown specifically teach the step of inserting a needle into a patient. Brown does teach that the apparatus may be used to detect blood loss, therefore, it would have been obvious to one having ordinary skill in the art use the apparatus adjacent to a needle in a patient they have inserted a needle into, since one of ordinary skill in the art would recognize that blood loss from a needle dislodgement could be very dangerous to the patient. Further, it would be beneficial to use the apparatus over a needle to alert the user/physician if the needle should become dislodged, since it is important to quickly correct a needle dislodgement to avoid air infiltration of the vessel.

Claims 23-26, 29, & 32-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown (5,036,859) in view of Kjellstrand et al. (Aksys, LTD-WO99/24145). Brown discloses the invention substantially as claimed, see rejection

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supra, however does not specifically teach that the apparatus is used during hemodialysis wherein a venous needle is used. Kjellstrand et al. disclose an extracorporeal circuit having a blood line separation warning device. The extracorporeal circuit may be a dialysis machine, which further has a computer control and alarm circuit that has a display. The blood line separation warning device has multiple electrodes connected via wires. Since Brown does teach that the apparatus may be used to detect blood loss, it would have been obvious to one having ordinary skill in the art use the apparatus, at the time of the invention, in a hemodialysis method, as taught by Kjellstrand et al., for detecting blood loss to immediately stop the procedure to avoid a catastrophic loss of blood.

Response to Arguments

Applicant's arguments filed 6/21/05 have been fully considered but they moot in view of the new ground(s) of rejection with respect to claim 12 (see rejection above).

Applicant argues that the disclosure of Brown "makes clear that the electrodes of the sensor contact the fluid to be sensed" and gives many examples where the fluid is urine. Applicant further argues that Brown does not teach or suggest a capacitive sensor that does not contact the fluid but instead teaches that its device requires contact between the fluid and the electrodes. Brown teaches of an embodiment that does not have a direct fluid-electrode communication and which is relied upon in the rejection above. As discussed in columns 8 to 9 and shown in figures 10-12, the apparatus has electrodes (130,132) are covered by an absorbent layer 125 or

electrodes (196,198) are covered by an absorbent layer 125 and additional, optional layer of highly absorbent material 190, such as cotton, is placed over the electrodes. The absorbent layer &/or additional material 190 absorbs the liquid and becomes electrically conductive to complete the circuit (col. 9, lines 1-11). Brown does states that "liquid urine must moisten the pad" to complete the circuit, but does not teach that the electrodes also contact fluid. Further, the recitation in the claims that the holder is "adapted to secure the sensor in juxtaposition to the needle" has not been considered since it has been held that the recitation that an element is "adapted to" perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchinson*, 69 USPQ 138.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia M. Bianco whose telephone number is (571) 272-4940. The examiner can normally be reached on Monday to Friday 9:00-6:30, alternate Fridays off.

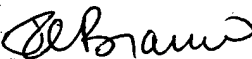
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

March 3rd, 2006

Patricia M Bianco
Primary Examiner
Art Unit 3761


PATRICIA BIANCO
PRIMARY EXAMINER